MAY 1 0 2001

K011084

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

April 9, 2001

2.1 General Information

2.1.1 Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 448-5111 Fax: (952) 448-3441

Contact Name: Jim Klosterman
Director of Quality Assurance/ Regulatory Affairs

2.1.2 Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as guides, guidewires, or spring guidewires. The current classification names, and product codes are Angiographic Guidewire (74HAP), Catheter Guidewire (74DQX), and Radiological Catheter Guidewire (74JAJ).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

The classification names listed above were originally classified as Class II devices by the Neurology (84HAD), Cardiovascular (74DQX) and Radiology (90JAJ) Review Panels, respectively.

2.1.6 Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

2.2 Labels, Labeling, and Advertising

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by

LRM. Changes to the customer controlled labels, labeling, or promotional material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Statement of Availability

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.4 Device Description

2.4.1 Nitinol or stainless steel core wire with stainless steel or platinum coil secured to the ground, flexible (distal) end of the core. The core wire can be either uncoated, coated with PTFE (polytetrafluoroethylene) or coated with PTFE-4 (poly aryl esther sulfone). Either portions of or the entire guidewire can also be subsequently coated with silicone MDX4-4159 Fluid. The guidewires are bound by the following parameters:

Outside Diameter: .014" - .045"
Lengths: 20cm – 500cm
Tips: Straight or shaped with various tip flexibilities
Coil Length: 2cm – 30cm

NOTE: None of these guidewires are for PTCA use.

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k) K971322]. The finished devices must meet the same basic design criteria.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined acceptance criteria.

Item	**Proposed Device Differences from LRM Predicate cleared under 510(k) K971322**
Raw Materials	Core: No change to raw material Coil: No change to raw material **Coating on core:** **Addition of poly aryl ether sulfone (PTFE-4) as an alternate coating option**
Assembly Process	No change to assembly processes

Physical Characteristics	No change
Labeling/IFU	**The only change to the label or IFU will be a name change. The name of the product will be "MANDREL GUIDEWIRE ASSEMBLY" instead of "CORE AND COIL GUIDEWIRE ASSEMBLY"**
Intended Use	No change to intended use
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

In order to demonstrate equivalence of the proposed device, LRM performed testing to established requirements. Configurations, including straight and shaped distal tips were inspected to established criteria. These parts were produced following current manufacturing processes and procedures.

2.5.2 Test Data
Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes.

The following tests were performed:

2.5.2.1 Visual: Assess the product for visual appearance per established criteria.

2.5.2.2 Dimensional Measurement – Outside Diameter of Core Body with PTFE-4 coating: Micrometer measurement of the outside diameter of the product at multiple body points.

2.5.2.3 Coating Durability: Measures the ability of the coating to adhere to the core wire material.

2.5.2.4 Pull Test: Measures the strength of materials and joints in the guidewire.

2.5.2.5 Distal Tip Flexibility: Assess the flexibility of the distal tip form of the product.

2.5.2.6 Lubricity: Measures the force required to insert and withdraw the guidewire within a shaped catheter lumen.

RESULTS: ALL TEST RESULTS WERE WITHIN PRESCRIBED SPECIFICATION LIMITS.

2.6 Qualification and Biocompatibility Test Data

2.6.1 Design Control

LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

2.6.2 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that each product manufactured with the PTFE-4 coated nitinol core material remain equivalent to the predicate products, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

2.6.3 Biocompatibility Testing

Biocompatibility testing has been performed on the material components of this device. This testing, along with a market history of proven biocompatibility establishes acceptable biocompatibility for this device.

2.7 Packaging and Sterilization Information

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. A portion of the production is private label, sterile packaged to customer specifications, a fraction of that product is provided sterile to the customer.

The single packaged mandrel guidewire is placed in a dispenser and then into a Tyvek®/poly pouch. The packaged product may be packaged as five or ten pouchs in a shelf carton, which are typical packaging configurations.

There will be no changes to the sterilization process for the portion of packaged product shipped sterile to the customer. For the product that is shipped bulk, the packaging design and sterilization process parameters are the customer's responsibility. LRM will not recommend that its customers modify their packaging or sterilization procedures as a result of this submission.

2.8 Intended Use Statement

To facilitate the placement of devices used during diagnostic and interventional procedures. **NOTE: The modification of this device does not alter its intended use.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2001

Mr. Jim Klosterman
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K011084
Mandrel Guidewires
Regulation Number: 870.1330
Regulatory Class: II (two)
Product Code: DQX
Dated: April 9, 2001
Received: April 10, 2001

Dear Ms. Klosterman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Mandrel Guidewires

Indications for Use:

To facilitate the placement of devices for diagnostic and interventional procedures.

NOTE: These guidewires are not intended for PTCA use.

for Division of Cardiovascular & Respiratory Devices
510(k) Number K011804

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ Or Over-The-Counter Use _____
(PER 21 CFR 801.109)

PREMARKET NOTIFICATION